PM-45

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 6 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#7E3489 - CGA-154281 on All Crops with Tolerances for Metolachlor (Dual®).
Evaluation of the Petition Method Validation Report.
(No MRID NO.)[No DEB NO.].{ No HED Project NO.}

FROM: Francis D. Griffith, Jr., Chemist
Dietary Exposure Branch
Health Effects Division (H7509C)

THRU: Robert S. Quick, Section Head
Tolerance Petition Section-I
Dietary Exposure Branch
Health Effects Division (H-7509C)

TO: Kerry Leifer, PM - 45
Registration Support Branch
Registration Division (H-7505C)

The Dietary Exposure Branch (DEB) has been informed by the Analytical Chemistry Section, Analytical Chemistry Branch (ACB) of the completion of the requested CGA-154281 petition method validation (PMV). The PMV was reported by Douglas M. Swineford in his memorandum dated May 30, 1989.

The PMV was requested for CGA-154281 [4-(dichloroacetyl)-3,4-dihydro-3-methyl-2H-1,4-benzoxozine] in corn forage (see memorandum by F. D. Griffith, dated March 8, 1989 to ACB/BEAD). The PMV for CGA-154281 on corn forage was requested for the Ciba-Geigy method AG-536A, dated June, 1989, and titled "Analytical Method for the Determination of CGA-154281 in Crops by Capillary Gas Chromatography."

The PMV was conducted using the petitioner's method as supplied by DEB. ACB encountered several problems during this tryout which ultimately led to the conclusion the method is not suitable for regulatory work. ACB's concerns/problems are as follows:

> "1. The submitted method for the quantitative analysis of CGA-154281 indicated that for the method to be successful it is imperative for the gas chromatographic (G.C.) standard used for quantitation be made with 20%

regulatory labs. These recommendations have been incorporated into the revised method AG-536C.

> "3. Analysis of 25g aliquot of corn forage control and corn forage control at 0.01 and 0.02 ppm by the submitted method did not allow for the separation and accurate quantitation of CGA-154281 from the background of the dorm forage matrix. The problem of high levels of interference for the analysis of corn fodder is also mentioned in comments number 6 Ciba-Geigy - Job #88-196 (Report #1)."

DEB concurs with ACB that crop coextractives or unidentified analytical responses (UAR's) can interfere with the identification and quantification of CGA-154281 in corn forage. The petitioner has now revised the clean up step of his method to include additional sample clean up.

DEB requested the CGA-154281 method be validated at 0.01 ppm and 0.02 ppm. No recoveries were reported due to positive UAR's and variable standard response. Based on standard responses the limit of detection should be less than 0.005 ppm. Without recoveries DEB concludes there has not been a successful petition method validation. The petitioner has revised the method along the lines discussed above and a new PMV has been initiated.

The analytical reference standard for CGA-154281 is available from EPA's Pesticides and Industrial Chemicals Repository at Research Triangle Park, NC. The code is F-927. DEB is aware that a new standard of CGA-154281 has been sent to the EPA lab in Beltsville. When the new PMV is initiated this new standard should be checked against the standard from RTP. There needs to be a comparison of standards to ascertain the Repository is in fact sending our CGA-154281.

ACB reported that a skilled analyst with all of the necessary equipment in place should be able to prepare a set of 6 samples within 8 hours and complete the analysis with ALS-GC overnight. This is consistent with the time frame the petitioner reported. While this time is satisfactory for regulatory work DEB defers judgement until the revised method has completed a PMV.

CONCLUSION

There has not been a successful PMV.

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